

Technology Assessment



**Technology
Assessment Program**

**An assessment of medical
literature evaluating inpatient
rehabilitation facility programs
on conditions of interest**

**Agency for Healthcare
Research and Quality
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Background

The Centers for Medicare and Medicaid Services (CMS) issued a final rule (69 FR 25752) on the classification criteria for qualification as an inpatient rehabilitation facility (IRF). As part of that rule, CMS is convening an expert panel to establish a research agenda towards obtaining data on the types of patients in other diagnostic categories who might show significant improvement from inpatient rehabilitation.

CMS requested a report from the Agency for Healthcare Research and Quality (AHRQ) to assess the availability and features of the medical literature evaluating inpatient rehabilitation facility on specific conditions of interest. This report will be used to inform a meeting of the expert panel.

Method

In consultation with AHRQ and CMS staff, and an NIH representative, the EPC developed the following inclusion criteria and conducted a literature review of the following conditions not currently listed in CFR Title 42 §412.23(b)(2)(iii).

Conditions of interest

- Cardiac
 - Ischemic heart disease (coronary artery disease)
 - S/P CABG or valve replacement surgery
 - Heart failure (ischemic or other causes)
 - Cardiomyopathies
 - Acute coronary syndrome

- Acute myocardial infarction (MI)
- Pulmonary
 - COPD – emphysema, chronic bronchitis and asthma
 - Restrictive lung disease – especially pulmonary fibrosis
 - Respiratory failure
 - S/P ventilator use
 - S/P pneumonia
- Transplant surgery
- Total joint (knee or hip) replacement
- Back surgery
- Cancer (including leukemias and lymphomas [excluding nervous system lesions], breast cancer [without metastases affecting the nervous system], lung cancer, and bowel cancer).

Settings of Interest

- Inpatient Rehabilitation Facilities
- Skilled Nursing Facilities
- Home Health Rehabilitation conducted in the home by a therapist
- Outpatient Rehabilitation

In some countries, there are specialized inpatient rehabilitation facilities that patients were transferred to after the acute care event. These differ from inpatient rehabilitation facilities and skilled nursing facilities in the US. Therefore, we created a

separate category of “specialized rehabilitation centers” in the tables to make this distinction.

No restriction was placed on the country or the year that the study was conducted. We acknowledge that studies conducted outside of North America may have limited applicability to the US healthcare setting. Similarly, studies conducted in the US 10 to 20 years ago may no longer be relevant due to rapidly changing healthcare practices. Given that few studies directly compared outcomes achieved at inpatient rehabilitation facilities with outcomes at skilled nursing facilities or outpatient settings, single arm cohort studies (subjected to additional criteria defined below) were also reviewed to acquire additional information.

Study categories

Studies that met the conditions and settings of interest were grouped into the following categories:

Category I – Studies comparing inpatient rehabilitation facilities with alternative care settings. Studies in this category provide the most reliable and direct evidence of the effects of inpatient rehabilitation. Studies that compared one inpatient rehabilitation facility with another inpatient rehabilitation facility or studies that compared different interventions at the same inpatient rehabilitation facility belong to this category. Comparisons of specialized inpatient rehabilitation centers with other facilities also belong here.

Category II – Other (non-inpatient rehabilitation facilities) comparison studies; include skilled nursing facility vs. home health rehabilitation and skilled nursing facilities vs. outpatient rehabilitation, and comparisons of other inpatient and outpatient settings.

Category III – Single-arm cohort studies in any rehabilitation setting. Because of few direct comparison studies comparing rehabilitation settings are available, results from single–arm cohort studies across different rehabilitation settings will be examined.

Categorization of Studies

	Inpatient Rehabilitation Facilities	Skilled Nursing Facilities	Home Health Rehabilitation	Outpatient Rehabilitation
Inpatient Rehabilitation Facilities	I	I	I	I
Skilled Nursing Facilities		II	II	II
Home Health Rehabilitation			NA	NA
Outpatient Rehabilitation				NA
Single Arm Cohorts	III	III	III	III

NA – Not applicable, comparisons in outpatient settings will not be evaluated

Inclusion Criteria for Categories I & II studies

Only comparative studies that report on patient outcomes were accepted for Categories I & II. These include randomized controlled trials (RCTs) and prospective or retrospective cohorts. Case series are excluded.

Inclusion Criteria for Category III studies

Acceptable studies for Category III include single-arm prospective or retrospective studies in any rehabilitation setting, and randomized controlled trials (used as cohorts) in the outpatient rehabilitation setting. Of particular interest are studies that reported outcomes related to independent living (i.e., percent living in community) at 6 months or later after the time of the event. The cancer literature will be analyzed only for studies that include cancer patients in inpatient rehabilitation facilities. Outpatient cardiac and pulmonary rehabilitation studies are excluded. In addition, home health rehabilitation studies that involve no supervision and are merely exercise programs for the patient to practice on their own are also excluded.

Data Extraction

We extracted the following information from each article that met the inclusion criteria:

- Year of publication
- Country where the study was performed
- Type of rehabilitation facility
- Number of patients evaluated

- Duration of follow-up
- Condition(s) treated
- Outcomes assessed
- Main study findings

The extracted information is summarized in 3 tables according to the study category. Within each table, RCTs are listed first, followed by prospective and then retrospective studies. The purpose of this report is to discover the scope of the literature currently available to address the conditions of interest. It is not the intent of this report to evaluate the efficacy of specific rehabilitation protocols or the benefits of specific type of rehabilitation facilities. Therefore, detailed outcomes data from these studies are not analyzed. A summary of the main study findings for each study is provided in the tables.

Literature search

We searched MEDLINE and CINAHL databases on November 9, 2004 and November 11, 2004, respectively for potentially relevant human studies published in English language. The literature search strategy and the search results are shown in Appendix A. In February of 2005, an additional study was brought to our attention by a panel of technical experts at a NIH meeting on Research Agenda on Appropriate Settings for Rehabilitation. This study is included in our results.

Results

The literature search identified 3,139 MEDLINE and 1,537 CINAHL English language abstracts. We screened 4,105 unique abstracts and retrieved 240 full articles for further evaluation. A total of 31 studies met the inclusion criteria. We identified 16 studies for Category I (Table 1), 1 study for category II (Table 2), and 14 studies for Category III (Table 3).

Category I studies include 8 RCTs, 3 prospective and 5 retrospective cohorts. These studies covered patients with MI, COPD, total knee or hip arthroplasty, and post-mastectomy for breast cancer.

Among the RCTs, 3 evaluated rehabilitation protocols in post-MI patients, 3 on total joint knee or hip arthroplasty, and 1 each on COPD and breast cancer (post-mastectomy). The number of patients randomized ranges from 25 to 296. Three of the RCTs were conducted in the US. The other RCTs were conducted in Austria, Italy, Scotland, Switzerland, and UK. Six of these RCTs were published since 1997. The last US RCT was published in 1998.

While there are 8 RCTs, only 1 trial with 60 patients conducted in UK compared inpatient rehabilitation with an outpatient program (Hill 2000). Patients in this study had total knee replacement and were randomized to early discharge followed by an orthopedic outreach team or standard inpatient rehabilitation. This trial followed patients for up to one-year and assessed knee performance and function score, as well as patient satisfaction. The other RCTs either compared variations of the inpatient interventions or with no treatment control. For example, a trial from Austria involving 296 patients compared computer-aided training with conventional training in an inpatient

rehabilitation program (Eisermann 2004). A study (Dubach 1997) from Switzerland randomized post-MI patients with congestive heart failure to 2 months of cardiac rehabilitation at a residential rehabilitation center or to a control group without any specific rehabilitation intervention in which exercise testing, blood pressure, and cardiac mass were evaluated as outcomes.

Two of the 3 prospective cohort studies in this category were conducted in Japan in post-MI patients. One of these cohort studies was reported more than 20 years ago. Due to the differences in the culture and healthcare practices for post-MI patients, the Japanese studies probably is of little relevance to the US healthcare environment. The single US prospective cohort of 100 patients published in 1999 compared subacute rehabilitation facility with home care in patients who underwent unilateral total joint arthroplasty (Kelly 1999).

Five retrospective studies compared inpatient rehabilitation with some form of outpatient rehabilitation or no rehabilitation, 2 studies addressed post-MI patients, 2 on COPD, and 1 on total hip or knee replacement. The single US study compared 50 inpatients who received daily rehabilitation sessions for 2 weeks with 84 outpatients who received 1 to 2 weekly 2-hour rehabilitation sessions for 2 months.

There is only 1 study in Category II, a RCT conducted in Hong Kong to determine the effects of community nurses using a care protocol in following up older nursing home patients with COPD after their discharge from the hospital. The main outcome measures were assessed at 6 months and included functional, respiratory, and psychological status, hospital service utilization, patients and nursing home staff satisfaction.

Category III studies are mostly non-comparative single arm studies and they are included to supplement information provided by comparative studies. A total of 14 studies belong to this category: 2 RCTs, 7 prospective cohorts, 4 retrospective studies, and 1 study that included both prospective and retrospective patients. The number of patients ranged from 12 (heart transplant) to 2,441 (cardiac rehabilitation). The 2 RCTs were conducted in Finland and Norway in patients who underwent lumbar disc surgery and compared different rehabilitation protocols in the outpatient setting. All of the non-randomized studies, except one study of outpatient rehabilitation of renal transplant recipients, were conducted in the inpatient or special rehabilitation center setting. COPD was the most common condition (7 out of 14 publications) reported by studies in this category. Four of the 7 COPD studies were conducted in the US, 3 of which were published more than 15 years ago. Outcomes reported by the COPD studies include pulmonary function, exercise tolerance, various quality of life scales, rehospitalization, length of stay, supplemental oxygen use, and survival. Both of the post-MI/cardiac surgery rehabilitation studies were conducted in specialized inpatient rehabilitation centers, one in Germany and one in Yugoslavia.

Conclusions

We summarized 31 studies in this report. There are only 17 Category I or II comparative studies relevant to the conditions of interest. Only 1 RCT compared rehabilitation programs at an inpatient rehabilitation facility and an outpatient setting. Overall, studies were heterogeneous in terms of the research question, condition of interest, type of rehabilitation facilities, country of origin, interventions, follow-up duration, and outcomes assessed. There is a paucity of comparative studies for each of the conditions of interest. Very few studies were conducted in the US within the past 10 years. Even though it is not the intent of this report, it would be difficult to draw reliable conclusions about the beneficial effects of different rehabilitation settings. Current data is insufficient, mostly outdated or irrelevant to inform clinical practice in the US. Many more high quality studies that directly compare inpatient rehabilitation with alternative rehabilitation settings for various conditions of interest are needed on the US population. These studies should fully report the characteristics of the rehabilitation setting and the protocols. These studies should also be adequately powered and follow patients for at least 6 months and report not only physiologic and clinical outcomes, but functional status and rate of return to the community as well.

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Table 1. Comparisons of inpatient rehabilitation facilities with skilled nursing facilities, outpatient, or home rehabilitation programs (Category I)

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Dubach 1997	Switzerland	RCT		X			X	25	2 mo	Post-MI with CHF	Exercise testing BP Cardiac mass	Increased exercise capacity (as estimated by oxygen uptake) in the exercise group vs. controls ($p<0.05$); no differences within or between groups on left ventricular volume, function or wall thickness	2 mo treatment at residential rehabilitation center (n=12) vs. control (n=13).
Eisermann 2004	Austria	RCT	X X					296	6 mo	Total knee 147 Total hip 149	Staffelstein Score Hanover Functional Ability Questionnaire Hospital for Special Surgery Score Harris Hip Score	Significant improvement for all score in each group; no differences concerning functional capacity between groups	Random assignment either to computer-aided training or conventional self-training within 3-4 weeks inpatient rehabilitation program
Hill 2000	UK	RCT	X			X		60	1 yr	Unilateral total knee arthroplasty	Clinical condition of joint: Knee score Functional score Patient satisfaction via self-administered questionnaire	Improvement within groups (NS); no differences concerning functional capacity between groups in the long run; greater satisfaction in intervention group; no differences in complications between groups	Identical care for both groups from admission to day 5, followed by separate treatment care via protocol Inpatient is the control group

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Johnston 1999	Scotland	RCT	X X				X	100	1 yr	Post MI	Mood: HADS; Satisfaction with care; Disability and resumption of normal activities; Functional Limitations Profile (FLP), Knowledge	More knowledge, less anxiety, less depression, and greater satisfaction with care in intervention group; also less disability as measured by FLP scores ($p<0.05$)	Compared inpatient care vs. extended care (extra 8 sessions) vs. normal care control
Munin 1998	US	RCT	X X					86	Up to 4 months	Hip or knee arthroplasty	LOS Cost analysis Functional & health status assessments	Shorter LOS ($P<0.04$) & lower mean total cost ($p<0.03$); more rapid attainment of short-term functional milestones between post-op day 6 and 10; equivalent functional outcome at 4-month follow-up	Begin inpatient rehab 3 day post-op vs. 7 day post-op
Nava 1998	Italy	RCT		X X				80	~35 d	COPD	LOS Death Pulmonary function/status	No significant between group LOS difference; 6-min walking distance and maximal inspiratory pressure were significantly improved only in intervention group; dyspnea (measured by VAS) significantly improved in both groups; not significant improvement in dynamic lung volumes	2 different rehabilitation protocols in rehabilitation center respiratory ICU ~35 d hospitalization

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Oldridge 1990	US	RCT	X X					51	28 d	Post MI	Hospital stay, Self-efficacy scores for Physical Activities; Self-efficacy scores for Daily Living tasks	Significant improvements in self efficacy scores in both groups for routine physical activities and daily living tasks with no change in self efficacy scores for concentration or ability to cope in the long run	Random assignment either to 2 inpatient rehabilitation programs: ward ambulation or exercise center
Wingate 1989	US	RCT	X X					115	~2.5 mo	Breast carcinoma (post mastectomy)	Shoulder abduction and flexion Hospital stay Post-op complications	Significant improvement in shoulder abduction and flexion for the treatment group vs. controls; no difference in hospital stay and complications	Random assignment either to immediate post-op physical therapy (n=61) or not (n=54)
Fujita 1983	Japan	Prospective cohort	X X					283	2 yr	Post MI	Exercise tolerance Working ability after discharge, LOS, Mortality	Significant improvement in exercise tolerance within each group but no difference between groups; no significant difference in working ability, LOS, and mortality	4 wk vs. 8 wk rehabilitation
Kelly 1999	US	Prospective convenient sample		X		X		100	3 mo	Unilateral total joint arthroplasty	Self-reported functional outcomes	All patients improved their scores without significant difference between the groups	Subacute facility vs. home- care

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Yoshida 2001	Japan	Prospective cohort	X X				X	85	12 mo	Post MI	Exercise tolerance Exercise frequency Spielberger State-Trait anxiety SRQ-D, QOL	Improvement in exercise tolerance for intervention groups at 6 mo maintained up to 12 mo follow up; higher percentage had physical activity in both intervention groups vs. controls at 6 mo maintained at 12 mo; significant improvement for lipid profiles in intervention groups; significant improvement for QOL scores for intervention groups vs. controls at 6 mo not maintained at 12 mo	Compared a 2-wk hospitalized phase II cardiac rehabilitation program with a previous 4 wk program vs. non participating control
Baessler 2001	Germany	Retrospective case-control	X				X	92 pairs	5.5 yr average	Post MI	CVD risk factors CVD events	Significant decrease in SBP and DBP for the rehabilitation group vs. controls; trend for lower lipid levels, smoking prevalence, and fewer CVD events in rehabilitation group vs. controls	Retrospective analysis of sibling pairs, comparing 2-4 wk in-hospital rehabilitation with sibling that didn't have rehabilitation
Clini 2001	Italy	Retrospective case-control	X			X		86	No data	COPD	Pulmonary physiologic outcomes, costs, fatigue measures	Significant improvement in cycloergometry peak workload in both groups without difference between cases and controls; higher total cost for controls; significant decrease in dyspnea and leg fatigue in both groups	IRF: 19 d (max 12 sessions) vs. Outpatient: >8 wk (max 24 sessions)

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Couser 1995	US	Retrospective review of medical records	X			X		134	~2 wk inpatient ~2 mo outpatient	COPD	12 min walk distance Education score	Significant improvement in 12 min walk distance, and educational self-assessment questionnaire score compared with values before rehabilitation	50 Inpatient: daily session for 2 wk; 84 Outpatient: 1 to 2 weekly 2-h sessions for 2 mo
Mahomed 2000	Canada	Retrospective cohort	X			X		146	8 mo	Total hip or knee arthroplasty	WOMAC, SF-36 & satisfaction score.	No significant differences for WOMAC, SF-36 & satisfaction score	89 inpatient rehabilitation vs. 57 home rehabilitation
Skof 2001	Slovenia	Retrospective cohort	X			X		320	5 yr median	Post MI	CVD risk factors (BP, lipids, BMI, glucose, etc.) Drug treatments	Significant lower smoking prevalence, diastolic BP, BMI, LDL, and total cholesterol in outpatient group vs. inpatients; no differences in systolic BP, HDL, triglycerides, and fasting blood glucose; higher percentage of patients consumed a protective diet, or being physically active in outpatient group vs. inpatients	180 patients attended outpatient university clinic 140 patients attended community hospital inpatient rehabilitation

IRF – intensive rehabilitation facilities; Rehab Ctr. – specialized rehabilitation centers; SNF – skilled nursing facilities; Out-Pt. – outpatient, No Rx – no treatment control

Table 2. Comparisons of skilled nursing facilities with outpatient or home rehabilitation (Category II)

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Lee 2002	Hong Kong	RCT			X X			89	6 mo	COPD	Readmissions/ hospital days/ ER visits, Pulmonary function, ADL and psychological scales	No differences between the 2 groups in functional and respiratory outcomes or hospital service utilization; experimental group had significant improvement in psychological well-being (assessed by GHQ)	Intervention: nursing home with care protocol Control: Either nursing home or outpatient without care protocol

IRF – intensive rehabilitation facilities; Rehab Ctr. – specialized rehabilitation centers; SNF – skilled nursing facilities; Out-Pt. – outpatient, No Rx – no treatment control

Table 3. Non-comparative cohort studies of inpatient, skilled nursing facilities, outpatient, or home rehabilitation (Category III)

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Alaranta 1986	Finland	RCT				X X		106	1 yr	Lumbar disc herniation surgery	Return to work, clinical lab tests	No significant differences in handicap distribution between the intervention and normal care arms	"Multifactorial rehab" for 2 weeks one month post-op vs. outpatient "ordinary therapy"
Danielsen 2000	Norway	RCT				X X		39	1 yr	Lumbar discectomy	Disability index, ADL, length of sick leave, pain	Self-reporting & Roland's disability index was significantly higher for the intervention arm, but no differences in clinical end points between the 2 arms	Compare aggressive exercise rehabilitation program vs. control (mild home exercise)
Carter 1988	US	Prospective cohort	X					59	3 mo	COPD	Pulmonary function, exercise tolerance, ventilatory gas exchange, work physiology	Significant improvement in peak work tolerance, resting ventilation did not change	Twice daily of 32-40 minutes of aerobic exercise conditioning
Connor 2001	Ireland	Prospective cohort	X					170	1 yr	COPD	Pulmonary function, exercise endurance, dyspnea measured by Borg scores, QOL measured by CRDQ, BPQ, SGHQ	Significant improvements in exercise tolerance, QOL and dyspnea	Patients initially admitted for 5 days followed by 7 wk of outpatient rehabilitation
Guyatt 1987	Canada	Prospective cohort	X					28	6 mo	COPD	Chronic respiratory disease questionnaire, pulmonary function, 6 minutes walk test	11 had sustained improvement on QOL and functional exercise capacity	4-6 wk inpatient stay
Moser 1980	US	Prospective cohort	X					42	At discharge & 4 weeks	COPD	Pulmonary function Max exercise levels and arterial blood gas, ADL	Post program heart rate, O ₂ consumption, minute ventilation, and respiratory rate were significantly reduced during exercise compared to baseline	

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Sabers 1999	US	Prospective cohort	X					189	At discharge	Cancer- all types	Discharge destination, Karnofsky score Bartel mobility index	Significant functional improvement was observed	Consultative interdisciplinary rehabilitation service for hospitalized cancer patients
Stewart 2001	US	Prospective cohort	X					157	At discharge	COPD	Rehospitalization, LOS, Pulmonary function, QOL discharge disposition, supplemental oxygen	Significant improvement: distance walked for ambulators, decrease in supplemental O ₂ use by bed-bound patients, improved QOL, improved knowledge of COPD, decreased admissions post compared to pre-program	Interdisciplinary inpatient rehabilitation program average stay 21 days
Willich 2001	Germany	Prospective cohort		X				2441	1 yr	Post-MI, CABG, PTCA	Recurrent clinical events CVD death and events, Cardiac risk factors, CVD medications	Significant decrease in use of aspirin, beta blockers, lipid-lowering meds, ACE inhibitors at 1 yr, 43% had clinical event, improvements in cardiac risk factors were not maintained at 1 yr	18 inpatient rehabilitation centers in Germany
Joshi 1997	US	Prospective/ retrospective chart review	X					12	At discharge	Heart transplant	Modified Barthel Index Score, LOS	Functional status scores improved significantly after rehabilitation	Patients transferred from transplant unit to an inpatient rehabilitation unit
Bebout 1983	US	Retrospective cohort	X					75	Mean 7.7 yr (range 2.4- 13.9)	COPD	Survival, QOL pulmonary function	Cumulative survival rate was 86.5% at 5 years of rehabilitation, and 64% at 10 years.	2 wk inpatient educational program and rehabilitation
Flores 1987	US	Retrospective cohort				X		142	1 yr	Renal transplant	Vocational status at 6 mo and 1 yr	60% fully rehabilitated, 7% in less than one year	

Author Year	Country	Study Design	IRF	Rehab Ctr.	SNF	Out-pt.	No Rx	Sample size	Follow-up Duration	Condition	Outcomes Assessed	Main Study Findings	Comments
Mok 2003	Hong Kong	Retrospective	X					53	1 yr	COPD	Hospitalization, Accident & emergency attendance, Functional status	No significant reduction in the rate of Accident and Emergency visits and length of stay for hospitalization one year pre and post- program	4 wk multidisciplinary inpatient pulmonary rehabilitation program
Turkulin 1988	Yugoslavia	Retrospective cohort		X				560	1 yr	Post-MI	Working capacity, LOS physical activity at work, stair climbing test, perception of health	Increased rate of re-employment for patients with higher work tolerance in exercise test and in patients who climbed to the second floor without symptoms at one year, higher educational level or positive assessment of health predictive of resumption of work	Specialized rehabilitation center

IRF – intensive rehabilitation facilities; Rehab Ctr. – specialized rehabilitation centers; SNF – skilled nursing facilities; Out-Pt. – outpatient ; No Rx – no treatment control

APPENDIX A. OVID MEDLINE search (1966-2004) November 9, 2004

#	Search History	Results
1	rehabilit\$.mp.	62137
2	inpatient.tw.	18775
3	exp rehabilitation centers/	7342
4	(hospital\$ or ward\$ or facilit\$ or center\$ or centre\$ or setting\$ or site\$ or unit\$ or clinic\$).tw.	2663919
5	1 and (2 or 4)	24422
6	3 or 5	29141
7	follow-up studies/	291794
8	(follow-up or followup).tw.	314480
9	exp Case-Control Studies/	268519
10	(case adj20 control).tw.	40895
11	exp Longitudinal Studies/	477456
12	longitudinal.tw.	57969
13	exp Cohort Studies/	511929
14	cohort.tw.	63980
15	(random\$ or rct).tw.	298879
16	exp Randomized Controlled Trials/	34992
17	exp random allocation/	52412
18	exp Double-Blind Method/	80608
19	exp Single-Blind Method/	8552
20	randomized controlled trial.pt.	196527
21	clinical trial.pt.	396471
22	controlled clinical trials/	2798
23	(clin\$ adj trial\$).tw.	82374
24	((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$ or mask\$)).tw.	77152
25	exp PLACEBOS/	23555
26	placebo\$.tw.	87143
27	exp Research Design/	186800
28	exp Evaluation Studies/	505882
29	exp Prospective Studies/	180965

30	exp Comparative Study/	1167424
31	or/7-30	2629109
32	6 and 31	11924
33	limit 32 to (human and english language)	9750
34	limit 33 to "all adult (19 plus years)"	7300
35	33 not 34	2450
36	limit 35 to "all child (0 to 18 years)"	582
37	33 not 36	9168
38	limit 37 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or guideline or interview or lectures or legal cases or legislation or letter or meta analysis or news or newspaper article or patient education handout or periodical index or practice guideline or "review" or review, academic or "review literature" or review, multicase or "review of reported cases" or review, tutorial)	1052
39	37 not 38	8116
40	stroke.mp.	60379
41	exp Spinal Cord Injuries/	22091
42	exp Nervous System Diseases/	1229696
43	exp Substance-Related Disorders/	141932
44	alcohol\$.mp.	170516
45	exp ALCOHOLISM/	48600
46	psychiatric.mp.	73489
47	exp AMPUTATION/	10722
48	dental.mp.	125971
49	exp Mental Disorders/	544381
50	or/40-49	1854720
51	39 not 50	3139